

Application No. 10/730,783  
Amdt. Dated August 18, 2008  
Reply to Office Action of May 16, 2008

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**REMARKS/ARGUMENTS**

**1. Remarks on the amendment**

Claim 11 has been amended to more specifically define Applicant's claimed invention.

Antecedent basis can be found in the Specification as filed. More specifically, antecedent basis of new Claim 11 can be found on page 20, third paragraph.

Applicant respectfully submits no new matter is introduced by the amendment.

**2. Response to the Rejection under 35 USC §103(a)**

Claims 11-16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Pearlman et al. (WO/9918800). This rejection is respectfully traversed by the amendment.

Applicant submits that nothing in the art of record teaches or suggests the subject matter positively recited in the amended independent Claim 11.

More specifically, as recited in the amended independent Claim 11, Applicant's claimed dermatological composition consisting of an avermectin compound in a concentration from about 0.05% to about 0.1% (w/v) in a lotion comprising glycerin, hydrogenated polyisobutene, cetearyl alcohol, polyoxyethylene ether of cetyl and stearyl alcohol, macadamia nut oil, dimethicone, tocopheryl acetate, stearoxytrimethylsilane, stearyl alcohol, panthenol, farnesol, benzyl alcohol, phenoxyethanol, acrylates/C10-30 alkyl acrylate crosspolymer, sodium hydroxide, citric acid, and water.

Pearlman et al. teach methods and kits for removing, treating or preventing head lice infestations in patients in need of such treatment, which includes topically applying to the lice-infested area an effective amount of a pediculostatic agent for a time sufficient to immobilize the lice, followed by combing to remove the lice and nits. This method optionally includes application of a pediculocide with the pediculostatic

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agent (see Abstract of the reference). Pearlman et al. further teach that pediculocides include pyrethrins, permethrin, lindane, malathion, carbaryl, ivermectin, and combinations thereof, at a concentration of from about 0.25% to about 2.5% (see page 19, third paragraph).

As expressly taught by Pearlman et al., the treatment causes desired immersion reflex starting from 6 seconds after the topical composition is applied, and the longest contact time of the composition is overnight (see page 4, the first and second paragraphs).

As further shown in the examples, among 31 patients involved in the treatment (once a week, with 2 to 60 minutes contact of the composition with the patients' hair), 7 achieved complete lice removal within 1 application, 19 achieved complete lice removal within 2 applications, 4 achieved complete lice removal within 3 applications, and 1 achieved complete lice removal within 4 applications (see page 24-28 of the reference).

In summary, Pearlman et al. teach to use Cetaphil lotion as a pediculostatic agent and optionally use ivermectin as a pediculocide at a concentration of from about 0.25% to about 2.5% to treat head lice for one or a few times, with a limited skin contact time with the topic composition.

Applicant points out Pearlman et al. teach substantially higher ivermectin concentration than that in Applicant's claimed composition. More specifically, the lowest concentration of ivermectin in Pearlman et al.'s composition is 2.5 times higher than the highest concentration of Applicant's claimed composition as defined in the amended Claim 11.

It is important to understand that Applicant's claimed composition is used for treating various forms of dermatological conditions, which requires daily application for a substantial period of time, i.e., from several weeks to several months. As demonstrated with extensive data in the instant Specification, Applicant has discovered that the instant dermatological composition containing a very low concentration of ivermectin from 0.05% to 0.1% is not only effective in treating transient acantholytic dermatitis, acne miliaris necrotica, acne varioliformis, perioral

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dermatitis, acneiform eruptions, acne vulgaris, or seborrheic dermatitis, but also does not cause skin irritation, or increase of skin sensitivity after daily use of the instant composition for a substantial period of time up to several months (see Examples 4-14, particularly Example 9).

As such, Applicant's topical composition containing a very low concentration of ivermectin in a lotion defined in Claim 11 has strong clinical advantages in treating the dermatological conditions described above.

Based on the above, it is apparent that Pearlman et al. fail to teach or recognize the need of using a low concentration of ivermectin in combination with a Cetaphil lotion. Applicant further points out where the prior art has not recognized the "result-effective" capability of a particular invention parameter, no expectation would exist that optimizing the parameter would successfully yield the desired improvement (*In re Antonie*, 559 F.2d 618, 195 USPQ 6, CCPA 1977).

Since Pearlman et al. teach a substantially higher ivermectin concentration for effective elimination of head lice, one of ordinary skilled in the art would not be motivated to try to use less than half of the lowest concentration taught by Pearlman et al.

Therefore, Applicant maintains that Applicant's claimed dermatological composition defined in the amended Claim 11 is unobvious in view of the prior art of record.

With regard to Claims 12-16, these claims are dependent upon independent Claim 11. Under the principles of 35 U.S.C. §112, 4th paragraph, all of the limitations of each independent claim are recited in its respective dependent claims. As described above, independent Claim 11 is not obvious, as such Claims 12-16 are submitted as being allowable over the art of record.

Accordingly, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. §103(a).

It is respectfully submitted that Claims 11-16, the pending claims, are now in condition for allowance and such action is respectfully requested.


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Applicant's Agent respectfully requests direct telephone communication from the Examiner with a view toward any further action deemed necessary to place the application in final condition for allowance.

8/18/2008  
Date of Signature

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